REMARKS

Claims 21-32 presently appear in this case. Claims 22-24 and 32 have been withdrawn from consideration. Claims 21 and 25-29 have been rejected. Claims 30 and 31 have been objected to. The official action of December 2, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to a method for treating autoimmune and inflammatory diseases against which administration of a TNF receptor is effective by administering a combination of the TNF receptor and DHEA.

Claims 22-24 and 32 remain withdrawn from consideration by the examiner. It is urged, however, that once generic claim 21 is found to be in condition for allowance then the withdrawn claims depending therefrom should be rejoined, examined and also allowed.

Claims 21 and 25-29 have been rejected under 35 U.S.C. §112, first paragraph, because the specification does not reasonably provide enablement for a method of treating autoimmune and inflammatory diseases by administration of a TNF receptor in combination with DHEA. The examiner states that the specification does not enable any person skilled in the art to practice the invention

commensurate in scope with these claims. The examiner states that while the art teaches that TNF receptor alone is effective for the treatment of RA, SLE and NOD mouse model of diabetes, this is not demonstrative of any and all autoimmune and inflammatory conditions, and does not enable one of skill in the art to treat any and all autoimmune and inflammatory conditions using the claimed method. This rejection is respectfully traversed.

In an attempt to obviate this rejection, claim 21 has now been amended to appear in Jepson-type format, with the known process in the preamble and the improvement in the body of the claim. This type of claim form is specifically permitted by 37 C.F.R. §1.75(e). The claim is now directed only to the treatment of autoimmune and inflammatory diseases against which a TNF receptor is effective. The improvement is administering the TNF receptor in combination with DHEA. The present application does not purport to disclose any new discoveries as to what diseases or conditions may be treated by TNF-R. The present invention is directed to the discovery that, for those diseases or conditions that are treatable by TNF-R, an even better effect will be obtained when the TNF-R is administered in combination with DHEA, either simultaneously, separately or sequentially. The known

effects of TNF-R are disclosed on pages 1 and 2 of the present specification.

Accordingly, none of the present claims read on any diseases or conditions against which TNF-R would be ineffective. The examiner may or may not be correct in stating that "TNF is not involved in all autoimmune and inflammatory disorders". However, even if this statement is true, the presently amended claims only read on those autoimmune and inflammatory disorders for which administration of a TNF-R is effective; the improvement is administering the TNF-R in combination with DHEA.

Accordingly, with this amendment to the claims, it is submitted that all of the present claims are now supported by an enabling disclosure and do not read on inoperative embodiments. Reconsideration and withdrawal of this rejection are therefore respectfully urged.

Claim 30 has now been amended to delete reference to septic shock, and instead to refer to the autoimmune diseases specified at page 3, lines 29-30, i.e., rheumatoid arthritis, lupus erythematosus, and multiple sclerosis. It is urged that claim 30 should still be considered to be in condition for allowance.

It is submitted that all the claims now present in the case clearly define over the references of record

and fully comply with 35 U.S.C. §112. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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